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June 26, 2013

Via ECF

The Honorable Douglas E. Arpert
U.S. District Court for the District of New Jersey
Clarkson S. Fisher Building & U.S. Courthouse
402 East State Street
Trenton, N.J. 08608

Re: *AstraZeneca/Pozen v. DRL, Lupin & Anchen*
Civil Action No. 3:11-CV-2317-JAP-DEA

Dear Judge Arpert:

As per Your Honor's instructions during the June 21, 2013 scheduling conference, DRL writes to explain why the "validity contentions" sent by Pozen on June 13, 2013 are improper and contravene this Court's Local Patent Rules. The Local Patent Rules permit a "response to invalidity contentions" when the accused infringer serves invalidity contentions. In the case at issue, DRL served no invalidity contentions. Pozen's "response" is therefore improper and should be stricken.

At the May 9, 2013 status conference, Pozen argued that its second vimovo case against DRL needed a new and discrete round of contentions under the Local Patent Rules. Accordingly, the Court entered a Scheduling Order (D.E. 145) specific to the second of the two DRL vimovo cases that required "DRL [to] disclose its invalidity and non-infringement contentions to Plaintiffs by May 23, 2013." *DRL disclosed only non-infringement contentions and disclosed no invalidity contentions.* As a result, unless DRL were to seek leave to amend its contentions, it cannot in this case argue invalidity – even if its Notice Letter raised that possibility. But unlike the ANDA product at issue in the first DRL vimovo case, DRL designed the ANDA product at issue here specifically to avoid infringement, and therefore this case does not need to reach the issue of invalidity. Accordingly, DRL did not serve invalidity contentions. Pozen nevertheless interposed validity contentions *despite DRL's decision to forgo any invalidity contentions.*

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During the June 21st telephone conference, Stephen Hash, on behalf of Pozen, argued that Pozen had a “duty and obligation” to submit “validity contentions” because DRL’s answer and Notice Letter referenced invalidity defenses. That is the only argument Pozen offers. That argument must fail because it renders L. Pat. R. 3.6(c) meaningless and undermines the main point of the contention process of the Local Patent Rules: to winnow the issues down and focus the case on fewer disputes. Surely Pozen does not contend that DRL, who failed to serve invalidity contentions, can nevertheless argue invalidity because its Notice Letter discussed invalidity. To the contrary, DRL would be required to seek leave of court to add invalidity contentions belatedly. If the Court were to permit belated invalidity contentions, the Court would then permit the patent holder to put in a “Response to Invalidity Contentions.” *See* L. Pat. R. 3.6(i). But an amendment to add invalidity contentions is not a matter of right. As Your Honor has held in several cases including this one, “the Local Patent Rules require parties to crystallize their theories of the case early in litigation and to adhere to those theories once they have been disclosed,” *King Pharms., Inc. v. Sandoz Inc.*, 2010 WL 2015258, at *4 (D.N.J. May 20, 2010). D.E. 134, p. 9.

Pozen’s stated excuse – “needing” to respond to DRL’s answer and Notice Letter – is therefore plainly untrue. What Pozen is apparently trying to do is to use the contention process of the second DRL vimovo case as a hook to refer to and use in the first DRL vimovo case the very contentions this Court refused Pozen leave to add into the first DRL vimovo case. *See* D.E. 134. But slipping those contentions into the second DRL vimovo case is inappropriate.¹ As this Court noted just three months ago in denying Pozen leave to amend contentions in the first DRL vimovo case, consolidation for discovery does not merge the various cases. D.E. 134, p 8 (“Plaintiffs, therefore, may not amend their responses simply to promote uniformity among the consolidated actions.”).

If Pozen thinks the existence of the second DRL vimovo case justifies an amendment to its contentions in the first DRL vimovo case, it should be forthright and say so. Then the proper path for Pozen would be to seek leave to amend its contentions in the first DRL vimovo case and not to pretend that assertions made in the Notice Letter or a three-line affirmative defense in an answer, *but that DRL never carried forward in any contentions*, somehow warrant Pozen’s 60-page “validity contention” response. If Pozen were to make such a motion, DRL could then respond to whatever arguments Pozen may make and the Court would have the merits of the issue presented.

¹ Incorporating the disputed validity contentions into the second DRL vimovo case is also pointless since DRL does not in the second DRL vimovo case claim the patent is invalid.

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There are seven prior versions of Pozen “validity contentions.”² This would be the eighth, and the fourth directed to DRL. Pozen’s effort to introduce yet another set of “validity contentions” through the back door must be rejected.

For all the reasons set forth here and in the D.E. 116, 129 and 134, the Court should strike Pozen’s June 14, 2013 “validity contentions” in their entirety. DRL encloses a Proposed Order for the convenience of the Court consistent with this request.

Respectfully submitted,



Alan H. Pollack

cc: Counsel of Record (by email)
attachment

² (1) Pozen’s original validity contentions to DRL; (2) Pozen’s original validity contentions to Lupin; (3) Pozen’s Proposed Amended validity contentions to Lupin; (4) Pozen’s Proposed Amended validity contentions to DRL; (5) Pozen’s “Compromise” validity contentions to Lupin; (6) Pozen’s proposed “Compromise” validity contentions to DRL; and (7) Pozen’s validity contentions to Anchen.

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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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|------------------------------------|---|--------------------------------------|
| ASTRAZENECA AB, ASTRAZENECA | : | Civil Action No. 11-2317 (JAP-DEA) |
| LP, and POZEN INC., | : | |
| Plaintiffs, | : | |
| v, | : | |
| DR. REDDY'S LABORATORIES INC. and: | : | |
| DR. REDDY'S LABORATORIES LTD., | : | |
| Defendants. | : | |
| ASTRAZENECA AB, ASTRAZENECA | : | Civil Action No. 11-04275 (JAP-DEA) |
| LP, KBI-E INC., and POZEN INC., | : | |
| Plaintiffs, | : | |
| v. | : | |
| LUPIN LTD. and LUPIN | : | |
| PHARMACEUTICALS INC., | : | |
| Defendants. | : | |
| ASTRAZENECA AB, ASTRAZENECA | : | Civil Action No. 11-06348 (JAP-DEA) |
| LP, KBI-E INC., and POZEN INC., | : | |
| Plaintiffs, | : | |
| v. | : | |
| ANCHEN PHARMACEUTICALS, INC., | : | |
| Defendants. | : | |
| ASTRAZENECA AB, ASTRAZENECA | : | Civil Action No. 13-00091 (JAP)(DEA) |
| LP, and POZEN INC., | : | |
| Plaintiffs, | : | |
| v, | : | |
| DR. REDDY'S LABORATORIES INC. and: | : | |
| DR. REDDY'S LABORATORIES LTD., | : | |
| Defendants. | : | |

[PROPOSED] ORDER STRIKING CONTENTIONS

WHEREAS, Defendants Dr. Reddy's Laboratories Inc. and Dr. Reddy's Laboratories Ltd. ("DRL") has, by letter dated June 26, 2013, moved to strike the contentions of Plaintiffs AstraZeneca AB, AstraZeneca LP, and Pozen Inc. ("Pozen"), entitled "ASTRAZENECA AB'S, ASTRAZENECA LP'S, KBI-E INC.'S, AND POZEN INC.'S RESPONSES TO DR. REDDY'S LABORATORIES, INC. AND DR. REDDY'S LABORATORIES, LTD.'S INVALIDITY CONTENTIONS PURSUANT TO L. PAT. R. 3.6(i)" and the associated chart entitled "PLAINTIFFS' RESPONSIVE

CONTENTIONS PURSUANT TO L. PAT. R. 3.4A(c) and 3.6(i)," both dated June 13, 2013;

WHEREAS, by letter dated June 28, 2013, Pozen opposed DRL's motion to strike the Pozen contentions described above;

THEREFORE, these matters, having come before the Court in the status conference conducted on June 21, 2013, and all parties having had a full opportunity to be heard through the letters described above:

IT IS on this ____th day of July, 2013,

ORDERED that the motion to strike the invalidity contentions described above is **GRANTED**.

DOUGLAS E. ARPERT
United States Magistrate Judge